TRUE METRIX AIR

BLOOD GLUCOSE MONITORING SYSTEM

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TRUE METRIX AIR

BLOOD GLUCOSE MONITORING SYSTEM

Owner's Booklet

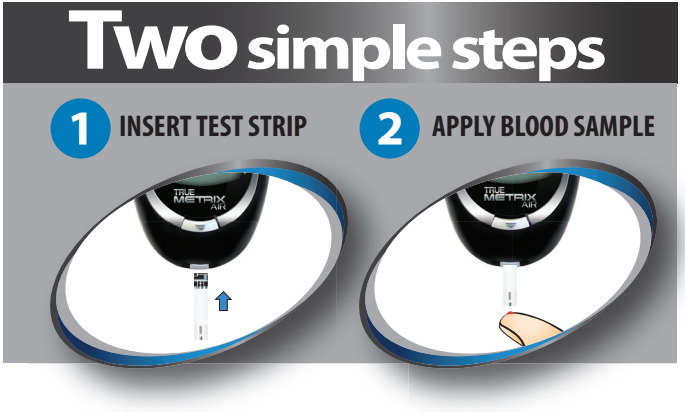
Bluetooth SMART

NO CODING

TRUE METRIX AIR

BLOOD GLUCOSE MONITORING SYSTEM

Fast Test Guide



For quick reference only, not intended as a substitute for complete instructions. Please read entire Owner's Booklet and product Instructions for Use before testing.

Expected Results for people without diabetes:[1]

	Plasma Blood Glucose Result
Before breakfast	< 5.6 mmol/L
Two hours after meals	< 7.8 mmol/L

The TRUE METRIX AIR Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh, human whole blood taken from the fingertip or forearm (capillary) and from the vein (venous). The System is intended for at-home use (self-testing by a single person and not shared) and for use by healthcare professionals for multiple patient use in professional healthcare settings. The system is not to be used on neonates or for the diagnosis or screening of diabetes mellitus. Alternate site testing can only be performed during steady-state blood glucose conditions. Testing is performed outside the body *(in vitro)* as an aid for monitoring the effectiveness of diabetes control.

Notes:

INTRODUCTION:

TRUE METRIX AIR

Blood Glucose Monitoring System

TRUE METRIX AIR is a simple, accurate way to test whole blood glucose (sugar) level, anytime, anywhere. Our goal is to provide quality healthcare products and dedicated customer service.

Importance of Blood Glucose Monitoring

A doctor or healthcare professional determines how often to test and what the target ranges are for blood glucose results. Having most blood glucose results within target range shows how well a treatment plan is working to control glucose levels. Keeping results within target range helps slow or stop complications from diabetes. **NEVER** change a treatment plan without consulting a doctor or healthcare professional.

SYMBOLS:

- Biological Risk
- STERILE R — Sterile
- Do Not Resterilise
- Single Use Only
- CONTROL — Control
- ① ② ③ Control Level
- SN — Serial Number
- Caution!
- Use By Date
- Keep Dry
- Attention! Read Instructions for Use.
- Storage Temperature Range
- Storage Humidity Range
- LOT — Lot Number
- IVD — For *in vitro* Diagnostic Testing Only
- EC REP — Authorised Representative
- Manufactured By
- Date of Manufacture
- Single patient use only
- Regulatory Compliance Mark (RCM)

IMPORTANT INFORMATION:

For the most accurate results using TRUE METRIX AIR:

- Read all product instructions for use before testing.
- Use of TRUE METRIX AIR in a manner not specified in this Owner's Booklet is not recommended and may affect ability to determine true blood glucose levels.
- TRUE METRIX AIR is an *in vitro* (outside body) IVD quantitative system that is used for self-testing of human whole blood only.
- Do not use TRUE METRIX AIR System during a xylose absorption test. This may falsely raise glucose results. Please check with your Doctor before using TRUE METRIX AIR.
- Do not use during xylose absorption testing, as xylose may produce falsely elevated glucose results during a xylose absorption test for diagnostic evaluation of malabsorption. Please check with a Doctor before using the System.
- Ascorbic acid (Vitamin C) greater than normal or therapeutic levels may cause significant interference resulting in inaccurate result.
- Uric acid can interfere with this device at normal and disease levels, when uric acid concentrations are greater than 0.3 mmol/L. For people with diabetes, certain conditions (including gout or kidney disease) may cause the blood level of uric acid to rise. This may cause significant interference resulting in inaccurate glucose results and the blood glucose results may be not reliable. Please check with a Doctor or Healthcare Professional before using the System.

IMPORTANT INFORMATION (cont.):

- Alternate site (forearm) testing should not be used to calibrate continuous glucose monitors (CGMs).
- Alternate site (forearm) testing should not be used for insulin dose calculations.
- Use only TRUE METRIX Test Strips and TRUE METRIX Control Solution with the TRUE METRIX AIR Meter.
- Remove only one test strip at a time from test strip vial. Recap vial immediately.
- NEVER reuse test strips. NEVER wipe test strips with water, alcohol or any cleaner. DO NOT attempt to remove blood or control solution from test strips or clean test strips and re-use. Reuse of test strips will cause inaccurate results.
- NEVER add a second drop of sample to test strip. Adding more sample gives an error message.
- Perform Control Tests ***before*** performing a blood glucose test for the first time.
- Perform Control Tests with more than one level of TRUE METRIX Control Solution. Three levels of control solution are available for Control Tests. Call 1800 001 351, 9:00am-5:00pm AEST, for assistance in obtaining control solution.
- Do not use for the diagnosis of or screening for diabetes mellitus or for measuring blood glucose in newborns.

FOR PATIENTS:

- DO NOT use on more than one person. **ALL** parts of the TRUE METRIX AIR Blood Glucose Monitoring System could carry blood-borne pathogens after use, even after cleaning and disinfecting.[2]
- The TRUE METRIX Blood Glucose Monitoring System is for one person use ONLY. DO NOT share your Meter or your Lancing Device with anyone, including family members.
- Wash hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets, or test strips as contact with blood presents an infection risk.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be cleaned prior to use by the second person.
- It is important to keep the meter and the lancing device clean. For instructions on how to clean the meter and lancing device, see *Meter Care* and *Cleaning and Lancing Device Care and Cleaning*.
- If there are symptoms of low or high blood glucose, check blood glucose immediately. If the result does not match the way you feel, repeat the test. If the results still do not match the way you feel, contact the doctor or healthcare professional.

~ Low blood glucose (hypoglycaemia) symptoms may be trembling, sweating, intense hunger, nervousness, weakness, and trouble speaking.

~ High blood glucose (hyperglycaemia) symptoms may be intense thirst, a need to urinate often, dry mouth, vomiting, and headache.

IMPORTANT INFORMATION (cont.):
FOR HEALTHCARE PROFESSIONALS:

- The TRUE METRIX AIR Blood Glucose Meter can be used on multiple patients. Healthcare Professionals always need to wear gloves and follow Cleaning/Disinfecting section and/or adhere to the infection control policies and procedures approved by their facility. The test strips and lancets are for single-use. Lancing device is restricted to be used on one patient only.
- Venous whole blood drawn into only a sodium or lithium heparin blood collection tubes or EDTA blood collection tubes must be used for testing. Mix well before use.
- DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing, as this may cause inaccurate results.
- Reuse of devices labeled for single-use may result in product contamination and patient infection.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be disinfected prior to use by the second person.
- **DO NOT perform capillary blood glucose testing on the critically ill.** Capillary blood glucose levels when critically ill with reduced peripheral blood flow may not reflect the true physiological state. Reduced peripheral blood flow may result from the following conditions (for example):[3]

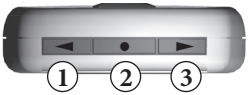
~ shock • severe hypotension • severe dehydration
~ hyperglycaemia with hyperosmolarity, with or without ketosis.

TABLE OF CONTENTS

Know Your System

Meter

Top of Meter



① **" ◄ " Button**

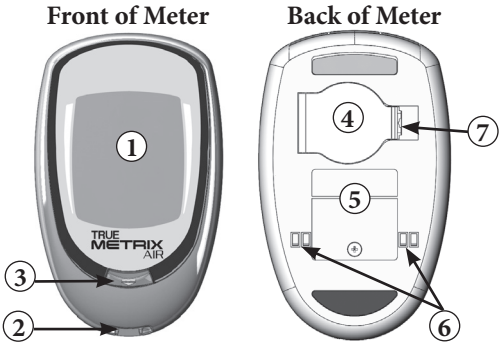
Increase numbers in Meter Set Up; remove ALT Symbol; move forward by date/time when viewing results and Averages in Memory; scroll through Event Tags to mark results (if feature on).

② **" • " Button**

Turn meter on to view Average values, view results in Memory, access Meter Set Up, turn on Event Tags in Meter Set Up, and turn on/off Bluetooth Smart.

③ **" ► " Button**

Decrease numbers in Meter Set Up; add ALT Symbol; move backward by date/time when viewing results and view Averages in Memory; scroll through Event Tags to mark results (if feature on).



① **Display Screen**
Shows results, messages, user prompts, information.

② **Test Port**
Insert Test Strip here, contact blocks facing up.

③ **Strip Release Button**
Releases test strip after testing for disposal.

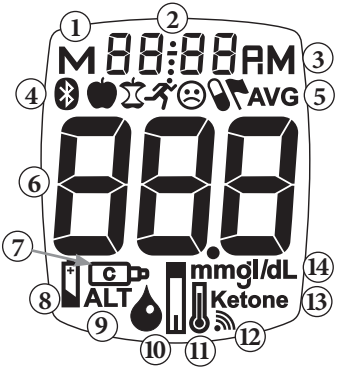
④ **Battery Door**
Use one non-rechargeable 3V lithium battery (#CR2032), positive ("+") side up (see *Changing Battery*).

⑤ **Meter Label**
Contains serial number of meter.

⑥ **Docking Station Contacts**
Connects meter with docking station for data upload to a computer.

⑦ **Tab Opening**
Insert a pointed tool in order to access lithium battery.

Full Display Screen



1. Result is from Memory
2. Time, Date
3. Time is AM/PM
4. Bluetooth Symbol and Event Tag Symbols
5. Result is 7, 14, 30, 60 or 90 day Average
6. Test Result
7. Control Symbol
8. Battery Symbol
9. Alternate Site (ALT) Symbol
10. Drop Symbol - Apply blood or control solution
11. Temperature Symbol
12. Test Reminder Symbol
13. Ketone Test Alert Symbol
14. Unit of Measure
    *(**Note:** Factory set, cannot be changed by user.)*

Test Strip

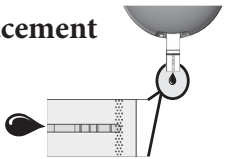
Top of Test Strip

① **Contact End** - Insert into Test Port with contact blocks facing up.

② **Sample Tip -** Bring Tip of test strip to top of sample drop (blood or control solution) ***after*** Drop Symbol appears in the Display.

Note: *Insert test strip into meter before touching Sample Tip to blood or control solution drop.*

Sample Placement

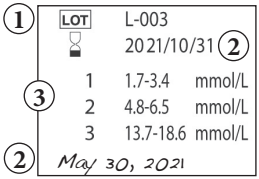


Correct

Incorrect

- Allow sample drop to be drawn into Sample Tip until testing begins (meter beeps and dashes move across Display).
- Do not smear or scrape drop with test strip.
- Do not apply more sample to test strip after testing begins.
- Do not apply blood or control solution to top of test strip.
- Do not insert Sample Tip with sample into Test Port. May damage meter.

Test Strip Vial Label



① **Lot Number (LOT)** - Used for identification when calling for assistance.

② **Use By Dates ( )** - Write date first opened on vial label. Discard vial and unused test strips if either 4 months after opening or date printed next to on vial label has passed, whichever comes first.

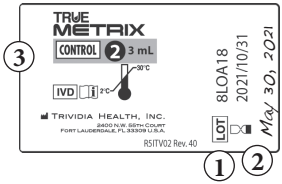
Use of test strips or control solution past the Use By Dates may give incorrect test results. Discard out-of-date products and test with new products.

③ **Control Test Range** - Range of numbers in which Control Test result must fall to assure the system is working properly.

Note: *Examples only. Do not represent actual Control Test ranges.*

Control Solution CONTROL

Control Solution Bottle Label



① **Lot Number (LOT)** - Used for identification when calling for assistance.

② **Use By Dates ( )** - Write date first opened on bottle label. Discard bottle if either 3 months after opening or date printed next to on bottle label has passed, whichever comes first.

③ **Control Solution Level (1, 2, or 3)** - We recommend testing at least 2 levels of control solution. Contact the number on the cover of this Booklet for information on how to obtain different levels of control solution.

Getting Started

Meter comes with pre-set time and date, and Bluetooth Smart feature on. The Event Tag feature, Ketone Test Alert, and all Test Reminders are off. Before using the meter for the first time or after a battery change, check the time, date, Bluetooth Smart, Event Tags, Alert and Reminders, and update as needed (see *Meter Set Up*).

The meter turns on when a test strip is inserted into the Test Port or when " • " Button is pressed (see *Memory* and *Meter Set Up*).

Meter turns off when the test strip is released or removed from the meter, " • " Button is pressed, or after 2 minutes of non-use.

The Bluetooth Smart feature turns off when a test strip is inserted into the Test Port or when meter is placed into docking station.

Turning the Ketone Test Alert on sets a reminder to check your ketones per your treatment plan when a blood glucose result is over 13.3 mmol/L.

Test Reminders are set like an alarm clock to sound a tone for 10 seconds to remind you to test. Up to four Test Reminders per day may be set.

Getting Started (cont.)

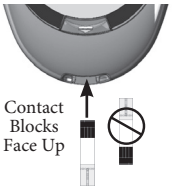
Event Tags allow you to tag your blood glucose results to link to the following events:

- Before meal –test was taken just before a meal,
- After meal –test was taken after a meal,
- Exercise – test was taken during or after exercise,
- Medications – medication taken may have affected test result,
- Sick – test was taken when sick,
- Other – any other reason that the test is unique or different in some way (example: stress, drinking alcohol). In your logbook, note the reason that the test result was tagged. Seeing a result with this Event Tag in the meter Memory reminds you that there is more about this test result in your log book.

Tagging results helps track the effect specific events may have on your blood glucose test results. Event Tagging may assist you and your doctor or healthcare professional provider with managing your diabetes.

Quality Control Testing

To assure you are getting accurate and reliable results, the System offers two kinds of quality Control Tests. These tests let you know that your System is working properly and your testing technique is good.



Automatic Self-Test

An Automatic Self-Test is performed by the meter each time a test strip is inserted correctly into the Test Port.

Insert a test strip into the Test Port.

The meter is working properly if:

- the full Display appears, then
- the time appears in the upper part of the Display, and then,
- the Drop Symbol begins to blink.

If an error message appears in the Display, the meter will not perform a test. See *Troubleshooting* or contact for assistance (see Booklet cover for contact information).

Full Display

Drop Symbol

Error Message

If any segments are missing in the Display when meter is first turned on, do not use the meter for testing. Contact for assistance.

Control Test

We recommend performing Control Tests to check the performance of the system.

Control Tests should be performed:

- To practice before using the system for the first time,
- For practice to ensure testing technique is good,
- Occasionally when using a vial of test strips,
- When opening a new vial of test strips,
- If results seem unusually high or low,
- If a vial has been left opened or exposed to extreme heat or cold, or humidity,
- Whenever a check on performance of the system is needed,
- If meter damage is suspected (meter was dropped, crushed, wet, etc.)

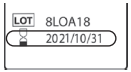
Note: It is important to perform Control Tests with more than one level of TRUE METRIX Control Solution. Three levels of control solution are available for Control Tests. Use contact on the cover for more information on how to obtain control solution.

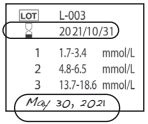
Ranges printed on test strip vial label are for Control Test results only and <u>are not</u> suggested levels for blood glucose. Do not drink control solution.

How to Test Control Solution

Use **ONLY** TRUE METRIX Control Solution with the TRUE METRIX AIR Meter and TRUE METRIX Test Strips.

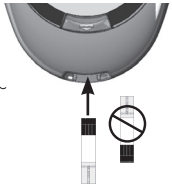
1. Check dates on control solution label and test strip vial label. Do not use control solution or test strips if either Use By Dates have passed. (control solution - 3 months after opening or date next to ⌛ on label, whichever comes first, test strips - 4 months after opening or date next to ⌛ symbol, whichever comes first.) Discard expired products and use new products.





2. Allow control solution, vial of test strips and meter to adjust to room temperature. Write date first opened on both control solution bottle label and test strip vial label when using for the first time.
3. Gently swirl or invert control solution bottle to mix.
   DO NOT SHAKE!
4. Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after removal from vial.

5. Insert test strip into Test Port. Meter turns on.



Contact Blocks Face Up

Note: *If test strip has been out of the vial too long before testing, an error message appears upon insertion of the test strip into the meter. Release and discard old test strip. Use new test strip for testing.*

6. Wait until Drop Symbol appears in Display. Keep test strip in meter until testing is finished.

Drop Symbol

Note: *If test strip is removed before testing is finished, an error message appears. Release and discard old test strip. Use new test strip for testing.*

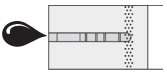
7. With cap removed, turn control solution bottle upside down. Squeeze one drop of control solution onto a clean tissue. Wipe off bottle tip and discard tissue.

8. Gently squeeze a drop of control solution onto a small piece of unused aluminum foil or clear plastic wrap. Dispose after use.

Discard Control Solution Drop on Tissue

9. With test strip still in meter, touch Sample Tip of test strip to top of drop of control solution. Allow drop to be drawn into test strip. Remove test strip from drop when meter beeps and begins testing.

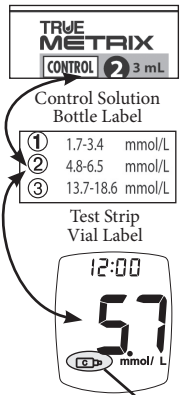
10. Dashes appear across the Display to show meter is testing.



Meter Testing

Note: *If meter does not beep and begin testing soon after drawing up sample, release and discard test strip. Repeat test with new test strip. If problem persists, see* Troubleshooting.

11. Compare meter result to Control Test range printed on test strip vial label for level of control solution you are using. If result is in range, system can be used for testing blood. If result does not fall within range, repeat test using a new test strip.

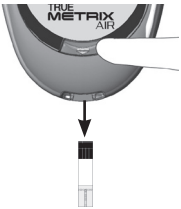


Control Symbol (Example only. Does not represent actual Control Test ranges)

Note: *Control Test result shows the Control Symbol in the Display.*

If Control Test result is outside range, test again. If result is still outside range, system should not be used for testing blood. Call for assistance (see Booklet cover for phone number).

12. After result is shown, Strip Release Button flashes. Hold meter with test strip pointing down. Press Strip Release Button to release and discard test strip into appropriate container. meter turns off.



Note: *Removing test strip before result displays cancels the test. An error message appears and the result is not stored in Memory. Retest with a new test strip and do not remove before result is displayed.*

TESTING BLOOD

Obtaining a Blood Sample

Refer to lancing device Instructions for Use for detailed instructions.

The lancing device is for single patient use ONLY. For cleaning your lancing device see lancing device's Instructions for Use. Wash your hands thoroughly with soap and warm water after handling the Meter, lancing device, or Test Strips. Contact with blood presents an infection risk.

- Never share lancets or lancing device. Lancets are for single use only. Do not re-use.
- To help prevent false high results, wash hands before using the system to test blood, especially after fruit has been handled.

From Fingertip

1. Prepare fingertip by washing hands in warm, soapy water. Rinse well. Dry thoroughly.
2. Place end of lancing device equipped with a lancet against tip of finger. Lance fingertip.


Lancing Finger

3. Set lancing device aside. To help blood drop form, lower hand to waist level, gently massaging finger from palm to fingertip. Allow blood drop to form for testing. Apply sample to test strip Sample Tip.
4. After testing, recap and remove used lancet from lancing device. Discard used lancet into appropriate container.

Treat used lancets as a biological risk. Dispose used lancets in approved container.

Tips for Forearm Sampling

Important Notes Regarding Forearm Testing[4]

- Check with the Doctor or Diabetes Healthcare Professional to see if forearm testing is appropriate.
- Results from the forearm are not always the same as results from the finger.
- Use finger for testing instead of forearm for more accurate results under the following conditions:

~ Within 2 hours of eating, exercise, or taking insulin,
~ If blood glucose may be rising or falling rapidly or their results often fluctuate,
~ If is ill or under stress,
~ If your forearm test results do not match how you feel,
~ If the glucose result may be low or high,
~ If symptoms of low or high glucose levels are not evident.

1. Select area. Clean the area with soap and warm water, rinse or use an approved disinfectant. Dry thoroughly.
2. Rub area vigorously or apply a warm, dry compress to increase blood flow.
3. Lance forearm. Apply sample to Sample Tip of test strip.
4. After testing, recap and remove used lancet from lancing device. Discard all biohazard materials into appropriate container.

Used test strips and lancets are considered biohazardous. Dispose used test strips and lancets into approved biohazard container.

From Vein

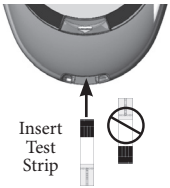
Venous whole blood drawn into only a sodium heparin or sodium lithium blood collection tubes or EDTA blood collection tubes must be used for testing. Mix well before use.

DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing. This may cause inaccurate results.

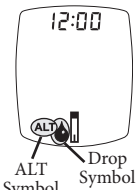
Used lancets and test strips are considered biohazardous. Please discard them according to the healthcare professional's instructions.

How to Test Blood

1. Check dates on test strip vial being used. Do not use if either 4 months after first opening or after date printed next to ⌛ on label, whichever comes first.
2. Wash hands (and forearm for alternative site testing). Rinse well and dry thoroughly.
3. Remove one test strip from vial. Close vial immediately. Use test strips quickly after removal from vial.
4. With meter off, insert test strip Contact End (blocks facing up) into Test Port. Meter turns on. Keep test strip in meter until testing is finished.



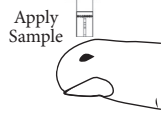
To mark test as alternate site (forearm) result, press " ► " Button. ALT Symbol appears in Display. Press " ◄ " Button to remove ALT Symbol.Wait until Drop Symbol appears in Display.



Note: *If test strip has been out of the vial too long before testing, an error message appears upon insertion of the test strip into the meter. Release and discard old test strip. Use new test strip for testing.*

5. Lance fingertip or forearm. Allow drop to form *(*see *Obtaining a Blood Sample).*

6. With test strip still in meter, touch Sample Tip of test strip to top of blood drop and allow blood to be drawn into test strip. Remove Sample Tip from blood drop immediately after the meter beeps and dashes appear across the Display.



Note: *If meter does not begin testing soon after touching Sample Tip to drop, discard test strip. Repeat test with new test strip and new blood drop. If problem persists, see* Troubleshooting.

7. Dashes appear across Display to show meter is testing.

8. After the test is finished, result is displayed. The Strip Release Button flashes.

Test Result

To mark the result with an Event Tag, make sure that Event Tags are turned on (see *Set Bluetooth Smart, Event Tags, Ketone Alert and Test Reminders*). The Event Tag icons flash.

Event Tag
(Before Meal Icon - *shown*)

Note: *Event Tag must be marked prior to the removal of test trip from meter.*

Press "►" or "◄" Button to go to the correct Event Tag. Press " • " Button to mark the test result with an event (icon stops flashing).

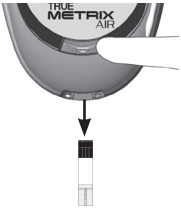

Top of Meter

Event Tags are as follows:

- Before meal –test was taken just before a meal,
- After meal –test was taken after a meal,
- Exercise – test was taken during or after exercise,
- Medications – medication taken may have affected test result,
- Sick – test was taken when sick,
- Other – any other reason that the test is unique or different in some way (example: stress, drinking alcohol). In your logbook, note the reason that the test result was tagged. Seeing a result with this Event Tag in the meter Memory reminds you that there is more about this test result in the log book.

Record result in log book.

9. Hold meter with test strip pointing down. Press test strip Release Button to discard test strip in the appropriate container. Meter turns off. Result is stored in Memory with date and time.



Note: *Removing test strip before result displays cancels the test. An error message appears and result is not stored in Memory. Retest with a new test strip and do not remove before result is displayed.*

Used lancets and test strips are considered biohazardous. Please discard them according to the healthcare professional's instructions.

System and Laboratory Testing

The most accurate glucose results come from using fresh, capillary whole blood from the fingertip. Capillary whole blood taken from the forearm or venous whole blood drawn into only a sodium heparin or sodium lithium blood collection tubes or EDTA blood collection tubes must be used for testing.

DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing, as this may cause inaccurate results.

When comparing results between TRUE METRIX AIR and a laboratory system, TRUE METRIX AIR blood tests should be performed within 30 minutes of a laboratory test. If you have recently eaten, fingerstick results from the TRUE METRIX AIR System can be up to 3.9 mmol/L higher than venous laboratory results.[5] Diabetes experts have suggested that 95% of glucose meter results agree within 0.83 mmol/L of a laboratory system when the glucose concentration is less than 5.55 mmol/L, and within 15% of a laboratory system when the glucose concentration is 5.55 mmol/L or higher.[6]

System Out of Range Warning Messages

Meter reads blood glucose levels from 1.1 - 33.3 mmol/L.

If blood test result is less than 1.1 mmol/L, "**Lo**" appears in meter Display.

If blood test result is greater than 33.3 mmol/L, "**Hi**" appears in meter Display.

ALWAYS repeat test to confirm Low ("**Lo**") and High ("**Hi**") results. If results still display "**Lo**" or "**Hi**", call the doctor or healthcare professional ***immediately***.

Note: *"**Lo**" results are included in the Average as 1.1 mmol/L.*
*"**Hi**" results are included as 33.3 mmol/L.*

If blood glucose test result is greater than 13.3 mmol/L and Ketone Test Alert is turned on, "Ketone" appears in Display with glucose result (see *Ketone Test Alert*).

Ketone Test Alert

When a Ketone Test Alert Symbol appears, it does not mean that ketones have been detected in the blood. Perform a ketone test per the treatment plan, as prescribed by the doctor or healthcare professional.

Note: *Ketone Test Alert can be turned on or off during Meter Set Up.*

Meter Set Up

Note: *If the meter turns off at any time during Set Up, go back to Step #1 under* Meter Set Up *and begin again.*

1. With meter off, press and hold " • " Button until the full Display is shown and a series of beeps sound (after about 10 seconds). Release " • " Button. Meter goes into Set Up.

Full Display

Set Time/Date

2. The hour flashes. To change, press " ► " or " ◄ " Button on top of the meter to select the hour. Press " • " Button to set.

Set Hour

3. The minutes flash. To change, press " ► " or " ◄ " Button to select the minutes. Press " • " Button to set.

Set Minutes

4. The month (number) flashes.
To change, press " ► " or " ◄ "
Button to select the month.
Press " • " Button to set.

Set Month

5. The day (number) flashes.
To change, press " ► " or " ◄ "
Button to select the day.
Press " • " Button to set.

Set Day

6. The year flashes.
To change, press " ► " or " ◄ "
Button to select the year.
Press " • " Button to set.

Set Year

Note: *Meter beeps every time a setting is confirmed (" • " Button is pressed).*

Set Bluetooth Smart, Event Tags, Ketone Alert and Test Reminders

Meter comes with Bluetooth Smart feature turned on. Event Tags, Ketone Test Alert and all Test Reminders are turned off.

Note: *If the meter turns off at any time during Set Up, go back to Step #1 under Meter Set Up and begin again.*

Bluetooth Smart

Uploading results using the Bluetooth Smart feature allows meter to send results to an application (App) on a paired smartphone. See Pairing (Syncing) Meter with Smartphone on page 39 for more information.

After setting the year, press " ► " or " ◄ " Button to turn on or off the Bluetooth Smart feature. Press " • " Button to set. Meter goes to set Event Tags.

Bluetooth Smart Enabled

Bluetooth Smart Disabled

Event Tags

Event Tags are used to mark a test result that was taken during a specific event.

1. After turning on or off the Bluetooth Smart feature, press " ► " or " ◄ " Button to turn Event Tags on or off. Press " • " Button to set, then the Meter goes to set Ketone Test Alert.

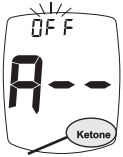
Top of Meter

Event Tags

Ketone Test Alert

When a blood glucose result is over 13.3 mmol/L, the Ketone Test Alert is a reminder to check your ketones per your treatment plan.

2. Press " ► " or " ◄ " Button to turn Alert on or off. Press " • " Button to set, then the Meter goes to set Test Reminder.



Ketone Test Alert

> ⚠ *When a Ketone Test Alert sounds, it does not mean that ketones have been detected in your blood. Perform a ketone test per your treatment plan, as prescribed by your Doctor or Healthcare Professional.*

Test Reminder

Up to four Test Reminders per day may be set. Reminder sounds at set time for 10 seconds. Meter comes with all Test Reminders off.

To set the Test Reminders:

Test Reminder

1. After pressing " • " Button to set Ketone Test Alert, Display shows first Reminder setting (A-1). To turn Reminder on, press " ► " Button. Press " ◄ " Button to turn Reminder back to off. Press " • " Button to set.

Set Hour

2. When "on" is chosen, press " • " Button. The hour flashes. Press " ► " or " ◄ " Button to set the hour. Press " • " Button to set.

3. The minutes flash. Press " ► " or " ◄ " Button to set the minutes. Press " • " Button to set. Meter goes to the next Test Reminder.

Set Minutes

4. Turn Reminders on and repeat setting the time for next 3 Reminders (if needed).

Exit Set-Up

Press and hold " • " Button until meter turns off. Meter also turns off after 2 minutes of non use. Set Up choices are saved.

Note: *If Test Reminders are set, the Alert Symbol appears in all Displays. If battery dies or is replaced, Ketone test alert and test reminders may have to be reset.*

Test Reminder Symbol

Meter Memory

View Averages

The Averages feature allows you to view the average of all your blood glucose results within a 7-, 14-, 30-, 60-, or 90-day period. Control Test results are not included in the Averages.

You can review the average of your glucose results from the last 7-, 14-, 30-, 60-, or 90-days.

1. With meter off press and release " • " Button. Display scrolls through 7-, 14-, 30-, 60-, and 90-day Average values.

7-Day Average

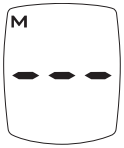
2. Meter turns off after 2 minutes if no buttons are pressed.

Note: *If there are no Average values, three dashes are displayed for 7-, 14-, 30-, 60-, and 90-day Averages.*

No Average

View Memory

Meter Memory stores 1000 results. When Memory is full, the oldest result is replaced with the newest result.



1. Press and release " • " Button. Meter displays 7-, 14-, 30-, 60-, and 90-day Averages. Press and release " • " Button again to view most recent test result in Memory. If there are no results in Memory, dashes appear with the Memory Symbol.
2. Press " ▶ " Button to scroll forward through results or " ◀ " Button to scroll backwards through results.

Test results marked as alternate site display **ALT** Symbol.

Control Test results display the Control Symbol. If no Control Test has been done, Display shows dashes and the Control Symbol.

Test results above 13.3 mmol/L display Ketone Test Alert Symbol, when Ketone Test Alert is turned on during Set Up.

Tests marked with an Event Tag shows the Event Tag icon in the Display.

Memory Symbol

Alternate Site Symbol

Control Symbol

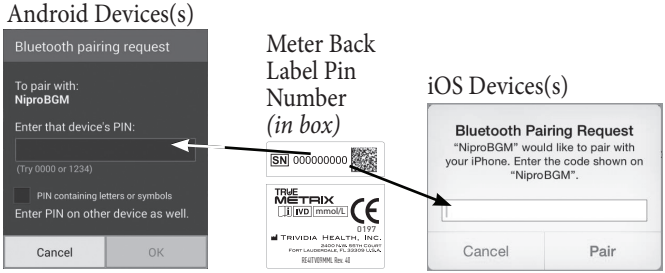
Ketone Test Alert Symbol

Event Tag
(Before Meal Icon - *shown*)

Pairing (Connecting) Meter with Smartphone

Pairing enables meter to upload test results when requested by an App (application) on smartphone. The meter must have the Bluetooth Smart feature turned on and smartphone must have an App that is able to receive the results. The meter and the smartphone must be within 10 feet of each other for the results to upload. The meter can be paired with up to four (4) smartphones.

1. Make sure that the Bluetooth Smart feature is turned on in the meter (see Bluetooth Smart on page 33).
2. Press " • " Button on the meter.
3. Follow smartphone instructions in order to locate TRUE METRIX AIR meter (look for a device named NiproBGM or TRUEAIR). Enter the last 6 digits of the meter serial number (found on meter back label) into the smartphone. This is the meter's PIN number. Wait for smartphone(s) to confirm connectivity. Once both devices are paired, you can have the App on the smartphone upload test results stored in the meter memory.



(Example only: shows pairing request for NiproBGM. Does not represent meter actual serial number.)

• If you make any changes through the meter set up, turn the meter off and start at Step #2 in order to be able to pair.

• Look for the Bluetooth icon  *on meter display to confirm it is turned on. You must first pair smartphone(s) with meter for test results to be uploaded.*

• This meter operates with Bluetooth Smart. Make sure that smartphone to be paired can work with Bluetooth Smart.

• Don't pair more than one smartphone to the meter at a time. If your meter has already paired with four (4) and is attempting to be paired with new smartphone, the smartphone paired first is replaced with the new smartphone.

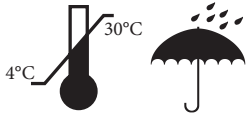
• If a test strip is inserted into the meter during the uploading of the results to the App, the results stop uploading. You must re-start the upload from the App installed on the smartphone.

WARNING!

- *To make sure that test results are secure, only let trusted people (doctor, family, etc.) download results to a computer program or connect to a mobile App.*
- *Keep meter serial number private.*
- *Allowing other people to download meter results to a computer or mobile Apps that is not yours could result in a loss of privacy of your data.*

System Care

- Store system (meter, control solution, test strips) in carrying case to protect from liquids, dust and dirt. Do not keep system in an area where it may be crushed (i.e. back pocket, drawer, bottom of bag, etc.).
- Store in a dry place at room temperature (4°C - 30°C) at 10%-80% relative humidity. **DO NOT FREEZE.**
- Allow system to sit at room temperature for 10 minutes before testing.



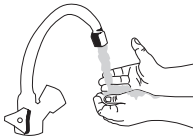
Meter Care, Cleaning/Disinfecting

Cleaning removes blood and soil from the meter.
Disinfecting removes most, but not all possible infectious agents (bacteria or virus) from the meter, including blood-borne pathogens.

- Clean immediately after getting any blood on the meter or if meter is dirty. Repeat if needed until all meter surfaces are visibly clean.
- Clean and disinfect the meter before allowing anyone else to handle it.
- Clean and disinfect meter at least once a week. Meter may be cleaned and disinfected once a week for up to 5 years.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be disinfected prior to use by the second person.
- Do not clean the meter during a test.
- Cleaning step #2 must occur before disinfecting steps #3 and #4.

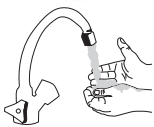
To Clean the Meter:

1. Wash hands thoroughly with soap and water.
2. Make sure meter is off and a test strip is not inserted. Rub the entire outside of the meter with a cleaning/disinfecting agent wipe with the active ingredients ammonium chloride with up to 0.25% of each quaternary ammonium compound and isopropyl alcohol (up to 55%). Do not use bleach. Rub the entire outside of the meter using 3 circular wiping motions with moderate pressure on the front, back, left side, right side, top and bottom of the meter. Make sure no liquids enter the Test Port or any other opening in the meter. Discard used wipes.



To Disinfect the Meter:

3. Using fresh wipes, make sure that all outside surfaces of the meter remain wet for 2 minutes.
4. Let meter air dry thoroughly before using to test.
5. Wash hands thoroughly again after handling meter.
6. Verify that the meter is working properly by performing an Automatic Self-Test. See *Automatic Self-Test* on how to perform.

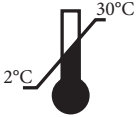


Stop using the Meter and use the contact information on the front cover for assistance if:

- Meter display appears cloudy or any display segments are missing,
- Markings on meter, including back meter label, are coming off or are missing,
- Buttons are hard to push on the meter or do not work,
- Unable to insert test strip into Test Port,
- Automatic Self-Test gives an error message.

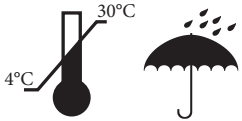
Control Solution Care

- Write date opened on control solution bottle label. Discard if either 3 months after opening or after date printed next to ⌛ on label has passed, whichever comes first.
- Store at room temperature (2°C-30°C). **DO NOT FREEZE.**
- After each use, wipe bottle tip clean and recap tightly.



Test Strip Care

- Store test strips in original vial only. Do not transfer test strips to new vial or store test strips outside of vial.
- Write date opened on test strip vial label. Discard unused test strips from vial if either 4 months after opening or after date printed next to ⌛ on label has passed, whichever comes first.
- Close vial immediately after removing test strip.
- Store in a dry place at room temperature (4°C-30°C) at 10%-80% relative humidity. **DO NOT FREEZE.**
- Do not reuse test strip.
- Do not bend, cut or alter test strips in any way.



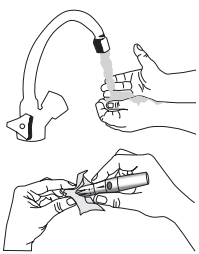
Lancing Device Care and Cleaning

Cleaning removes blood and soil from the lancing device.
Disinfecting removes most, but not all possible infectious agents (bacteria or virus) from the lancing device, including blood-borne pathogens.

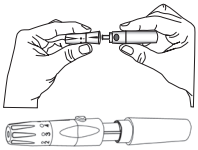
- Clean and disinfect immediately after getting any blood on the lancing device or if lancing device is dirty.
- Clean and disinfect the lancing device at least once a week. Lancing device may be cleaned and disinfected once a day for a 3 year period.
- If the lancing device is being operated by a second person who provides testing assistance, the lancing device should be disinfected prior to use by the second person.
- Do not clean lancing device if there is a lancet inside. Remove lancet from lancing device before cleaning.
- Cleaning step #2 must occur before disinfecting steps #3 and #4.

To Clean and disinfect the Lancing Device:

1. Wash hands thoroughly with soap and water.
2. **To Clean:** Remove End Cap. Clean with cleaning agent. Repeat as needed until all surfaces are visibly clean.
3. **To Disinfect:** Using fresh wipes, make sure that all outside surfaces of the lancing device remain wet for 2 minutes.



4. Let lancing device air dry thoroughly before using to test. Replace End Cap. Gently pull back Arming Barrel and press the Trigger Button. A click will be heard if the lancing device is functioning properly.
5. Wash hands thoroughly again after handling the lancing device.



Stop using the lancing device and use the contact information on the cover for assistance if:

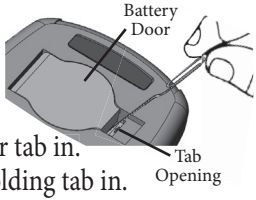
- Markings on lancing device are coming off,
- Trigger button hard to push,
- End Cap does not go back on,
- Arming Barrel does not click when gently pulled back.

Changing Battery

A low battery displays Battery Symbol while continuing to function. A dead battery displays Battery Symbol, beeps, and then turns off. To replace battery:


Low

Note: *Use non-rechargeable 3V lithium battery (#CR2032).*



1. Insert a pointed tool (e.g. small flathead screwdriver or paper clip) into the battery door/ cover tab opening compartment.
2. Using tool, press battery door/cover tab in.
3. Lift up battery door/cover while holding tab in.
4. Turn meter over, tap gently on the palm of your hand to loosen and remove battery.
5. Discard old battery into appropriate container.
6. Insert new battery, positive ("+") side facing up. Close Battery Door.
7. Press " • " Button to turn meter on. Check time, date, and Test Reminders (see *Meter Set Up*). If meter does not turn on, check that battery was installed properly. If not, remove and reinsert battery. Turn meter on by pressing " • " Button. Call for assistance if problem persists.

Note: *If battery is out of meter or dead too long, meter may reset to original factory settings. Verify settings are correct after replacing battery by, going into Meter Set Up and checking time, date, Ketone Testing Alert, and Testing Reminders. Change if needed. Results in Memory are not deleted and time and date on the results does not change if battery is dead or removed for any length of time.*

Battery is not rechargeable. If you have a cable and/or a cradle for downloading results to a computer, ***DO NOT*** *plug the cable end into an adaptor for an electrical outlet or use any other type of charger. Trying to recharge the battery or power the meter by plugging into an electrical outlet will cause meter to catch on fire or melt.*

Battery might explode if mishandled or incorrectly replaced. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local/country specific regulations.

Always have a spare battery. Be mindful that battery life may be affected by factors such as temperature and battery manufacturer. Have a back-up testing method available.

KEEP BATTERIES OUT OF REACH OF CHILDREN

- *Swallowing may lead to serious injury in as little as 2 hours or death, due to chemical burns and potential perforation of the esophagus.*
- *If you suspect your child has swallowed or inserted a button battery immediately call the 24-hour Poisons Information Centre on 13 11 26 for fast, expert advice.*
- *Examine your meter and make sure the battery compartment is correctly secured, i.e. the battery door is fully closed. If the battery compartment cannot be secured, remove the battery and keep away from children. Call Trividia Health Australia Customer Care 1 800 001 351 for assistance.*
- *Dispose of used button batteries immediately and safely. Flat batteries can still be dangerous.*
- *Tell others about the risk associated with button batteries and how to keep their children safe.*

Troubleshooting

1. ***After inserting test strip, meter does not turn on.***

Reason	Action
Test strip inserted upside down or backwards	Remove test strip. Re-insert correctly.
Test strip not fully inserted	Remove test strip. Re-insert test strip fully into meter.
Test strip error	Repeat with new test strip.
Dead or no battery	Replace battery.
Battery in backwards	Battery positive (“+”) side must face up.
Meter Error	Contact for assistance.

2. ***After applying sample, test does not start (meter does not beep or begin testing).***

Reason	Action
Sample drop too small	Repeat test with new test strip and larger drop.
Sample applied after two minute shut-off	Repeat test with new test strip. Apply sample within 2 minutes of inserting test strip.
Problem with test strip	Repeat with new test strip.
Problem with meter	Contact for assistance.

Use contact information on cover for assistance.

3. *Meter Bluetooth Smart feature is enabled but test result was not received by smartphone.*

Reason	Action
Smartphone containing App linked to the meter not turned on.	Turn on the smartphone.
Bluetooth Smart on the smartphone is turned off.	Turn on Bluetooth Smart on the smartphone.
Meter not linked with specific smartphone.	Link (pair) meter with smartphone.
Meter and smartphone are too far apart.	Bring smartphone and meter within 10 feet of each other.
Smartphone does not support Bluetooth Smart	Unable to use with smartphone.
App not compatible with Bluetooth Glucose profile[7]	Download compatible mobile App.

Note: *Any interruption in transmission may cancel the transfer of test results from meter to the smartphone. Results are re-transmitted the next time a data transfer is started.*

Use contact information on cover for assistance.

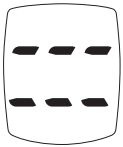
Messages

Display	Reason	Action
	Invalid Haematocrit	Repeat with new test strip, using capillary whole blood from the finger, forearm or venous whole blood collected only in a sodium heparin blood collection tube. If error persists, contact for assistance.
	Temperature error • Too cold/ Too hot	Move meter and test strips to area between 5°C-40°C; wait 10 minutes for system to reach room temperature before testing.
	Sample not detected or using wrong test strip	Retest with new test strip and larger sample.
	Used test strip; Test strip outside of vial too long; Sample on top of test strip.	Repeat with new test strip. Make sure Sample Tip of test strip touched top of sample drop. If error persists, contact for assistance.

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, contact for assistance.

Display	Reason	Action
	Meter error	Contact for assistance.
	Test strip error or very high blood glucose result (higher than 33.3 mmol/L)	Retest with new test strip. If error persists, contact for assistance. If symptoms such as fatigue, excess urination, thirst, or blurry vision are found, follow healthcare professional's advice for high blood glucose.
	Test strip removed during test	Retest with new test strip. Make sure result is displayed before removing test strip.
	Communication error	Contact for assistance.
	Low or dead battery	Low: About 50 tests can be done before battery dies. Dead: Battery Symbol appears and beeps before meter turns off.

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, contact for assistance.

Display	Reason	Action
	Broken Display	Do not use meter for testing. Contact for assistance.
 	⚠ **Out of range** **- High results** > 33.3 mmol/L **- Low results** < 1.1 mmol/L	⚠ Retest with new test strip. If result is still "Hi" (High) or "Lo" (Low) contact doctor or healthcare professional ***immediately***.

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, contact for assistance.

Performance Characteristics[8]

Precision: Precision describes the variation between results. There are two types of precision results measured, repeatability (using blood) and intermediate precision (using control solution).

Repeatability: N=100

Mean (mmol/L)	2.4	4.8	8.0	11.3	17.8
SD (mmol/L)	0.09	1.16	0.24	0.39	0.49
%CV	3.9	3.3	3.0	3.4	2.7

Intermediate Precision: N=100

Mean (mmol/L)	2.1	6.4	18.4
SD (mmol/L)	0.1	0.2	0.6
%CV	4.3	3.2	3.4

System Accuracy: Diabetes experts have suggested that 95% of glucose meter results should agree within $\pm$ 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and within $\pm$ 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L. The tables below show how often healthcare professionals (HCP) and users achieve these goals using capillary fingertip and forearm blood samples when glucose results are not fluctuating. The laboratory reference instrument is the Yellow Springs Instrument (YSI).

For Healthcare Professionals

99.3% of TRUE METRIX AIR fingertip values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Fingertip Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
99/156 (63.5%)	135/156 (86.5%)	155/156 (99.4%)

Fingertip Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
207/444 (46.6%)	364/444 (82%)	441/444 (99.3%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
596/600 (99.3%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

100% of TRUE METRIX AIR forearm values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Forearm Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
13/41 (31.7%)	26/41 (63.4%)	41/41 (100%)

Forearm Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
17/59 (28.8%)	38/59 (64.4%)	59/59 (100%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
100/100 (100%)

Parkes Error Grid: 100% of individual forearm glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

Venous Blood
96.4% of TRUE METRIX AIR venous values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Venous Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
16/50 (32%)	39/50 (78%)	50/50 (100%)

Venous Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
33/174 (19%)	100/174 (57.5%)	166/174 (95.4%)

Venous Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
216/224 (96.4%)

Parkes Error Grid: 100% of individual venous glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

For Consumers
99% of TRUE METRIX AIR fingertip values performed by users fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Fingertip Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
9/18 (50%)	17/18 (94.4%)	18/18 (100%)

Fingertip Samples (User vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
39/82 (47.6%)	65/82 (79.3%)	81/82 (98.8%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
99/100 (99%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

98% of TRUE METRIX AIR forearm values performed by users fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Forearm Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
21/41 (51.2%)	32/41 (78%)	41/41 (100%)

Forearm Samples (User vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
21/59 (35.6%)	39/59 (66.1%)	57/59 (96.6%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
98/100 (98%)

Parkes Error Grid: 100% of individual forearm glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

User Performance Evaluation: A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:
100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 98.8% within ± 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

System Specifications

Result Range: 1.1 - 33.3 mmol/L
Sample Size: 0.5 microlitre (0.5 µL)
Sample: Fresh capillary whole blood, venous whole blood collected in sodium or lithium heparin blood collection tubes or EDTA blood collection tubes, or control solution
Test Time: Results in as little as 4 seconds
Result Value: Plasma values
Assay Method: Amperometric
Power Supply: One 3V lithium battery #CR2032 (non-rechargeable)
Battery Life: Approximately 1000 tests or 1 year
Automatic shut-off: After two minutes of non-use
Weight: 47 grams
Size: 8.7 x 5.5 x 1.7 cm
Memory Size: 1000 glucose results and 1 control result
Operating Range (Meter & Test Strips For Blood Testing):

Relative Humidity: 10-90% (Non-condensing)
Temperature: 5 - 40°C
Haematocrit: 20-70%
Altitude: Up to and including 3109 metres

Note: *Use within specified environmental conditions only.*

Wireless Frequency: 2.4 GHz Band
Max Radio-Frequency Power Transmitted: 4dBm (2.5 mW)
Device Compatibility: Smartphones running applications compatible with Bluetooth Glucose Profile[7]

Chemical Composition

Test Strips: Glucose dehydrogenase-FAD *(Aspergillus sp.)*, mediators, buffers and stabilizers.
Control Solution: Water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

System Safety Information

Electromagnetic Compatibility

This meter meets the electromagnetic compatibility requirements as per EN ISO 15197:2015 and EN 300 328. It meets the electromagnetic emissions requirements as per EN 61326 series and EN 301 489-1 and EN 301 489-17.

Interference from the meter to other electronically driven equipment is not anticipated. The electromagnetic environment should be evaluated prior to operation of the device.

- *Do not use the meter in a very dry environment, especially one in which synthetic materials are present.*
- *Do not use the meter close to sources of strong electromagnetic radiation, as these may interfere with the proper operation.*

References

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3. Atkin, S. H., Dasmahapatra, A., Jaker, M.A., Chorost, M. I., Redd, S., *Fingerstick Glucose Determination in Shock.* Annals of Internal Medicine, 114:1020-1024, 1991.
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6. European Committee for Standardization. *In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus.* Reference number EN ISO 15197:2015 (E). Brussels: European Committee for Standardization; 2015.
7. Bluetooth Special Interest Group, Adopted Bluetooth Profiles, Glucose Profile https://www.bluetooth.org/en-us/specification/adopted-specifications.
8. Data on file.

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